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***Counsel's information continued on page i***

IN THE UNITED STATES DISTRICT COURT  
FOR THE CENTRAL DISTRICT OF CALIFORNIA

REGENERON PHARMACEUTICALS,  
INC., a New York corporation,

Plaintiff,

v.

AMGEN INC., a Delaware corporation,

Defendant.

Case No.

**COMPLAINT**

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COMPLAINT

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18 Regeneron Pharmaceuticals, Inc.

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1 Plaintiff Regeneron Pharmaceuticals, Inc. for its Complaint in this matter,  
2 alleges as follows:

### 3 **INTRODUCTION**

4 1. Plaintiff Regeneron Pharmaceuticals, Inc. (“Regeneron” or  
5 “Plaintiff”), invented, developed, and sells EYLEA<sup>®</sup>, the market-leading treatment  
6 for several serious eye diseases. Defendant Amgen Inc. (“Amgen” or “Defendant”)  
7 is seeking FDA approval under the Biologics Price Competition and Innovation Act  
8 (“BPCIA”), 42 U.S.C. §§ 262(k)-(l), to commercialize “ABP 938,” a proposed  
9 biosimilar of EYLEA<sup>®</sup>. To vindicate its patent rights, Regeneron brings this  
10 Complaint pursuant to 42 U.S.C. §§ 262(l)(6)(A), (9)(A) seeking a judgment of  
11 patent infringement against Amgen under 35 U.S.C. § 271(e).

12 2. Regeneron is a leading science-based American biotechnology  
13 company. With a focus on patient access and fair drug pricing, Regeneron is  
14 dedicated to innovation, improving human health, and tackling the most urgent  
15 medical issues facing the Nation. Founded and led for over 30 years by physician-  
16 scientists, Regeneron has developed life-transforming medicines for people with  
17 serious diseases, including cancer, atopic dermatitis, asthma, eye diseases,  
18 cardiovascular and metabolic diseases, Ebola, and COVID-19, which have been  
19 used across the country. Regeneron’s cutting-edge scientific advances are  
20 supported, in large part, by its ophthalmic product, EYLEA<sup>®</sup>, which FDA approved  
21 in 2011.

22 3. EYLEA<sup>®</sup> has been administered millions of times to treat  
23 certain ophthalmic disorders that, if left untreated, can lead to permanent blindness.  
24 Its active ingredient is a genetically engineered fusion protein called aflibercept. It  
25 works by blocking the overproduction of a naturally occurring protein in the eye  
26 that can cause the formation of new blood vessels, leading to vision loss. Based on  
27 extensive clinical testing by Regeneron, FDA approved EYLEA<sup>®</sup> in 2011 to treat  
28 an ophthalmic disorder called neovascular (wet) age-related macular degeneration



Patent	Issue Date	First Named Inventor
9,222,106	December 29, 2015	Gang Chen
9,254,338	February 9, 2016	George D. Yancopoulos
9,315,281	April 19, 2016	Tikiri Jean Dissanayake
9,816,110	November 14, 2017	Ying Shen
10,130,681	November 20, 2018	George D. Yancopoulos
10,415,055	September 17, 2019	Gang Chen
10,464,992	November 5, 2019	Eric Furfine
10,669,594	June 2, 2020	Serge Monpoeho
10,828,345	November 10, 2020	George D. Yancopoulos
10,888,601	January 12, 2021	George D. Yancopoulos
10,905,786	February 2, 2021	Philip Shodder
10,918,754	February 16, 2021	Philip Shodder
11,066,458	July 20, 2021	Eric Furfine
11,084,865	August 10, 2021	Eric Furfine
11,104,715	August 31, 2021	Shawn Lawrence
11,160,918	November 2, 2021	Andrew Cook
11,253,572	February 22, 2022	George D. Yancopoulos
11,306,135	April 19, 2022	Shunhai Wang
11,459,374	October 4, 2022	Andrew Tustian
11,472,861	October 18, 2022	Shawn Lawrence
11,505,593	November 22, 2022	Shunhai Wang
11,535,663	December 27, 2022	Shawn Lawrence
11,542,317	January 3, 2023	Shunhai Wang
11,548,932	January 10, 2023	Shunhai Wang
11,555,176	January 17, 2023	Wei Xue
11,559,564	January 24, 2023	George D. Yancopoulos

Patent	Issue Date	First Named Inventor
11,680,930	June 20, 2023	Nathan Mao
11,707,506	July 25, 2023	George D. Yancopoulos
11,753,459	September 12, 2023	Shunhai Wang
11,769,597	September 26, 2023	Lorah Perlee
11,788,102	October 17, 2023	Ying Shen
11,793,926	October 24, 2023	Andrew Cook

### **DEFENDANT**

7. Amgen Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen is, among other things, engaged in the development of biosimilar drugs, including a proposed biosimilar version of Regeneron's EYLEA®, ABP 938.

8. Upon information and belief, Amgen, directly or indirectly, manufactures its drug products within the United States and abroad. Upon information and belief, Amgen directly, or via its subsidiaries, affiliates, or other agents, develops, distributes, or sells within the United States or imports into the United States Amgen's drug products, including ABP 938, under the general direction and control of Amgen.

9. Amgen already has biosimilars that have been introduced into the United States market. For example, Amgen is the holder of a Biologics License Application for Amjevita, an approved biosimilar of Humira. Amgen Inc. also manufactures Amjevita.

10. On information and belief, Amgen and its subsidiaries, affiliates, and agents will function as an integrated organization and a single business enterprise in the manufacture of ABP 938, in the importation of ABP 938

1 into the United States, and in the sale or offer for sale of ABP 938 in the United  
2 States.

3 11. On information and belief, Amgen and its subsidiaries,  
4 affiliates, and agents develop, manufacture, distribute, sell, and/or import drug  
5 products for the entire United States market and do business in every state,  
6 including California, either directly or indirectly.

7 **JURISDICTION AND VENUE**

8 12. This action arises under the BPCIA, 42 U.S.C. § 262(l) and the  
9 Patent Laws of the United States, Title 35 of the United States Code. This Court  
10 has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1332, and 1338.

11 13. Amgen is a corporation organized and existing under the laws  
12 of the State of Delaware and has its corporate headquarters located at One Amgen  
13 Center Drive, Thousand Oaks, California 91320-1799. Amgen's office located at  
14 this address is a regular and established place of business within the forum.

15 14. Amgen is listed with the Office of the California Secretary of  
16 State as an entity that is currently doing business in the State of California, and the  
17 office of the California Secretary of State has assigned Amgen the following  
18 business entity number: C1579467. The Office of the California Secretary of State  
19 business listing for Defendant states the physical address of Amgen is One Amgen  
20 Center Drive, Thousand Oaks, CA 91320.

21 15. Amgen is a corporate entity currently doing business in the State  
22 of California and having a regular established place of business within the forum,  
23 Amgen purposefully engaged in activities that are directed at the forum, the action  
24 arises out of or relates to those activities, and the assertion of personal jurisdiction  
25 in the forum comports with traditional notions of fair play and substantial justice.  
26 For at least this reason, the Court has jurisdiction over Amgen in this action.

27 16. This Court also has personal jurisdiction over Amgen because  
28 Amgen is seeking approval to engage in the commercial manufacture, use, offer for



1 sale, sale, and/or importation of ABP 938 in the United States, including in the State  
2 of California; and because, if its product receives FDA approval, Amgen intends to  
3 market, distribute, offer for sale, and/or sell it in the United States, including in the  
4 State of California, deriving substantial revenue therefrom.

5 17. In addition, Amgen has consented to jurisdiction in the Central  
6 District of California in one or more prior cases arising out of its manufacture, use,  
7 offer for sale, sale, and/or importation of Amgen pharmaceutical products in the  
8 United States, including in the State of California. This includes cases Amgen has  
9 initiated as the plaintiff.

10 18. Venue is proper in this district under 28 U.S.C. § 1391(b)  
11 because Amgen Inc. resides in this District and a substantial part of the events and  
12 injury giving rise to Plaintiff's claims has and continues to occur in this District.

### 13 **FACTUAL ALLEGATIONS**

14 19. The BPCIA provides a mechanism to obtain FDA approval for  
15 a biological product that is "biosimilar" to a previously licensed "reference  
16 product" such as EYLEA®. 42 U.S.C. § 262(k). In order to be approved,  
17 biosimilars must be "highly similar to the reference product notwithstanding minor  
18 differences in clinically inactive components," with "no clinically meaningful  
19 differences between the biological product and the reference product in terms of  
20 the safety, purity, and potency of the product." *Id.* § 262(i)(2)(A)-(B).

21 20. The BPCIA reduces substantially the time and expense  
22 otherwise required to gain FDA approval, by allowing a biosimilar applicant like  
23 Amgen to rely on most of the prior clinical testing that Regeneron conducted to  
24 establish the safety and efficacy of the reference product (EYLEA®). Regeneron,  
25 the reference product sponsor, invested many years of effort into its design and  
26 development of EYLEA® and received patents rewarding this research. In  
27 exchange for this accelerated and far less expensive application process, the BPCIA  
28 obligates a biosimilar applicant to address a reference product sponsor's relevant



1 patents in a manner that permits adjudication of patent rights before  
2 commercialization of the biosimilar product. The BPCIA does so, *inter alia*,  
3 through a set of pre-litigation exchanges or steps outlined in 42 U.S.C. § 262(l)  
4 (herein referred to as the “patent dance”).

5           21. Amgen initiated the Patent Dance by serving Regeneron with  
6 its aBLA pursuant to 42 U.S.C. § 262(l)(2)(A) (“Amgen’s Production”). Amgen’s  
7 Production failed to satisfy § 262(l)(2)(A) because, for example, Amgen’s  
8 Production did not contain “other information that describes the process or  
9 processes used to manufacture the biological product that is the subject of such  
10 application,” as required by 42 U.S.C. § 262(l)(2)(A). Additionally, a number of  
11 documents in Amgen’s Production included inactive hyperlinks to underlying  
12 documents. These deficiencies impaired Regeneron’s review of Amgen’s  
13 Production and its ability to engage in the patent dance.

14           22. 42 U.S.C. § 262(l)(9)(A) provides that, “[i]f a subsection (k)  
15 applicant provides the application and information required under paragraph  
16 (2)(A), neither the reference product sponsor nor the subsection (k) applicant may,  
17 prior to the date notice is received under paragraph (8)(A), bring any action under  
18 section 2201 of title 28 for a declaration of infringement, validity, or enforceability  
19 of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).”  
20 Regeneron later notified Amgen that its Production was deficient in several ways  
21 that frustrated Regeneron’s review, and requested that Amgen produce specified  
22 information.

23           23. Despite Amgen’s numerous deficiencies, Regeneron timely  
24 served on Amgen “a list of patents for which the reference product sponsor believes  
25 a claim of patent infringement could reasonably be asserted by the reference  
26 product sponsor” (“3A List”) under § 262(l)(3)(A). Each of the Asserted Patents  
27 identified below was included on Regeneron’s 3A List.

1           24. In response to Regeneron’s 3A List, Amgen purported to  
2 provide a statement pursuant to 42 U.S.C. § 262(l)(3)(B)(ii)(I) (“3(B) Statement”).  
3 Amgen’s purported 3(B) Statement failed to provide a detailed statement  
4 describing, on a claim by claim basis, the factual and legal basis for its opinion that  
5 the patents on Regeneron’s 3(A) List are invalid or will not be infringed as required  
6 under § 262(l)(3)(B)(ii) and by the Federal Circuit’s decision in *Amgen Inc. v.*  
7 *Hospira, Inc.*, 866 F.3d 1355, 1362 (Fed. Cir. 2017). Rather, the contentions in  
8 Amgen’s 3(B) Statement were often conclusory or lacking supporting citation.

9           25. In response to Amgen’s purported 3(B) Statement, Regeneron  
10 timely provided a detailed statement that described, with respect to each patent  
11 described in Amgen’s purported 3(B) Statement, on a claim by claim basis, the  
12 factual and legal basis for Regeneron’s opinion that such patent will be infringed  
13 by the commercial marketing of ABP 938 and a response to Amgen’s purported  
14 3(B) Statement concerning invalidity (“3(C) Contentions”). 42 U.S.C. §  
15 262(l)(3)(C).

16           26. In Regeneron’s letter attaching its 3(C) Contentions, Regeneron  
17 began the negotiations specified under 42 U.S.C. § 262(l)(4)(A) and offered to  
18 confer with Amgen. Amgen’s counsel responded to say that they were not  
19 immediately available. Two weeks later, Regeneron followed up on its earlier  
20 proposal pursuant to 42 U.S.C. § 262(l)(4)(A), and offered to confer with Amgen  
21 on any day that week. Amgen did not respond. Three days later, Regeneron wrote  
22 to Amgen again by email, following up on its earlier messages and asking for  
23 Amgen’s position.

24           27. Later that day, Amgen responded with a letter accepting  
25 Regeneron’s original proposal pursuant to 42 U.S.C. § 262(l)(4)(A), thereby  
26 concluding the parties’ negotiations. 42 U.S.C. § 262(l)(6)(A) provides that “[i]f  
27 the subsection (k) applicant and the reference product sponsor agree on patents as  
28 described in paragraph (4), not later than 30 days after such agreement, the

1 reference product sponsor shall bring an action for patent infringement with respect  
2 to each such patent.” Amgen’s letter accepting Regeneron’s proposal was sent not  
3 more than 30 days from the filing of this complaint.

4 28. Accordingly, Regeneron timely brings this action pursuant 42  
5 U.S.C. § 262(l)(6)(A) for a judgment of infringement under 35 U.S.C. 271(e) with  
6 respect to the agreed-upon patents.

7 **CLAIMS FOR RELIEF**

8 **COUNT 1: INFRINGEMENT OF U.S. PATENT NO. 9,222,106 UNDER 35**  
9 **U.S.C. § 271(e)**

10 29. Regeneron incorporates by reference all of the allegations set forth above  
11 as if fully set forth below.

12 30. United States Patent No. 9,222,106 (“the ’106 patent”) (Exhibit 1  
13 hereto), was duly and legally issued on December 29, 2015.

14 31. Regeneron is the owner of all right, title, and interest in the ’106 patent.

15 32. The ’106 patent has not yet expired.

16 33. The ’106 patent claims methods of making biological products and was  
17 included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C.  
18 § 262(l)(3)(A).

19 34. The submission of Amgen’s aBLA to obtain FDA approval to engage in  
20 the commercial manufacture, use, offer for sale, and/or sale, or import into the United  
21 States, of ABP 938 before the expiration of the ’106 patent is an act of infringement  
22 of one or more claims of the ’106 patent under 35 U.S.C. § 271(e)(2)(C)(i).

23 35. For example, on information and belief, the manufacture, use, offer for  
24 sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*,  
25 claim 20 of the ’106 patent.

26 36. Regeneron will be irreparably harmed if Amgen is not enjoined from  
27 infringing one or more claims of the ’106 patent. Regeneron is entitled to injunctive  
28

1 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
2 from any further infringement. Regeneron has no adequate remedy at law.

3 37. Amgen's commercial manufacture, use, offer for sale, and/or sale within  
4 the United States, or importation into the United States, of ABP 938 before the  
5 expiration of the '106 patent will cause Regeneron injury, entitling Regeneron to  
6 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

7 38. The submission of Amgen's aBLA to obtain FDA approval to engage in  
8 the commercial manufacture, use, offer for sale, and/or sale within the United States,  
9 or importation into the United States, of ABP 938 before the expiration of the '106  
10 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

11 **COUNT 2: INFRINGEMENT OF U.S. PATENT NO. 9,254,338 UNDER 35**  
12 **U.S.C. § 271(e)**

13 39. Regeneron incorporates by reference all of the allegations set forth above  
14 as if fully set forth below.

15 40. United States Patent No. 9,254,338 ("the '338 patent") (Exhibit 2  
16 hereto), was duly and legally issued on February 9, 2016.

17 41. Regeneron is the owner of all right, title, and interest in the '338 patent.

18 42. The '338 patent has not yet expired.

19 43. The '338 patent claims methods of treatment using biological products  
20 and was included on the list of patents provided by Regeneron to Amgen pursuant to  
21 42 U.S.C. § 262(l)(3)(A).

22 44. The submission of Amgen's aBLA to obtain FDA approval to engage in  
23 the commercial manufacture, use, offer for sale, and/or sale, or import into the United  
24 States, of ABP 938 before the expiration of the '338 patent is an act of infringement  
25 of one or more claims of the '338 patent under 35 U.S.C. § 271(e)(2)(C)(i).

26 45. For example, the sale of ABP 938 pursuant to the label proposed in  
27 Amgen's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of  
28 the '338 patent.





1 States, of ABP 938 before the expiration of the '110 patent is an act of infringement  
2 of one or more claims of the '110 patent under 35 U.S.C. § 271(e)(2)(C)(i).

3 65. For example, on information and belief, the manufacture, use, offer for  
4 sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*,  
5 claim 18 of the '110 patent.

6 66. Regeneron will be irreparably harmed if Amgen is not enjoined from  
7 infringing one or more claims of the '110 patent. Regeneron is entitled to injunctive  
8 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
9 from any further infringement. Regeneron has no adequate remedy at law.

10 67. Amgen's commercial manufacture, use, offer for sale, and/or sale within  
11 the United States, or importation into the United States, of ABP 938 before the  
12 expiration of the '110 patent will cause Regeneron injury, entitling Regeneron to  
13 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

14 68. The submission of Amgen's aBLA to obtain FDA approval to engage in  
15 the commercial manufacture, use, offer for sale, and/or sale within the United States,  
16 or importation into the United States, of ABP 938 before the expiration of the '110  
17 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

18 **COUNT 5: INFRINGEMENT OF U.S. PATENT NO. 10,130,681 UNDER 35**  
19 **U.S.C. § 271(e)**

20 69. Regeneron incorporates by reference all of the allegations set forth above  
21 as if fully set forth below.

22 70. United States Patent No. 10,130,681 ("the '681 patent") (Exhibit 5  
23 hereto), was duly and legally issued on November 20, 2018.

24 71. Regeneron is the owner of all right, title, and interest in the '681 patent.

25 72. The '681 patent has not yet expired.

26 73. The '681 patent claims methods of treatment using biological products  
27 and was included on the list of patents provided by Regeneron to Amgen pursuant to  
28 42 U.S.C. § 262(l)(3)(A).







1 91. Regeneron is the owner of all right, title, and interest in the '992 patent.

2 92. The '992 patent has not yet expired.

3 93. The '992 patent claims biological products and was included on the list  
4 of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(l)(3)(A).

5 94. The submission of Amgen's aBLA to obtain FDA approval to engage in  
6 the commercial manufacture, use, offer for sale, and/or sale, or import into the United  
7 States, of ABP 938 before the expiration of the '992 patent is an act of infringement  
8 of one or more claims of the '992 patent under 35 U.S.C. § 271(e)(2)(C)(i).

9 95. For example, the manufacture, use, offer for sale, and/or sale within the  
10 United States, or importation into the United States, of ABP 938 will infringe, *inter*  
11 *alia*, claim 1 of the '992 patent.

12 96. Regeneron will be irreparably harmed if Amgen is not enjoined from  
13 infringing one or more claims of the '992 patent. Regeneron is entitled to injunctive  
14 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
15 from any further infringement. Regeneron has no adequate remedy at law.

16 97. Amgen's commercial manufacture, use, offer for sale, and/or sale within  
17 the United States, or importation into the United States, of ABP 938 before the  
18 expiration of the '992 patent will cause Regeneron injury, entitling Regeneron to  
19 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

20 98. The submission of Amgen's aBLA to obtain FDA approval to engage in  
21 the commercial manufacture, use, offer for sale, and/or sale within the United States,  
22 or importation into the United States, of ABP 938 before the expiration of the '992  
23 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

24 **COUNT 8: INFRINGEMENT OF U.S. PATENT NO. 10,669,594 UNDER 35**  
25 **U.S.C. § 271(e)**

26 99. Regeneron incorporates by reference all of the allegations set forth above  
27 as if fully set forth below.

1           100. United States Patent No. 10,669,594 (“the ’594 patent”) (Exhibit 8  
2 hereto), was duly and legally issued on June 2, 2020.

3           101. Regeneron is the owner of all right, title, and interest in the ’594 patent.

4           102. The ’594 patent has not yet expired.

5           103. The ’594 patent claims methods of detecting biological contaminants and  
6 was included on the list of patents provided by Regeneron to Amgen pursuant to 42  
7 U.S.C. § 262(l)(3)(A).

8           104. The submission of Amgen’s aBLA to obtain FDA approval to engage in  
9 the commercial manufacture, use, offer for sale, and/or sale, or import into the United  
10 States, of ABP 938 before the expiration of the ’594 patent is an act of infringement  
11 of one or more claims of the ’594 patent under 35 U.S.C. § 271(e)(2)(C)(i).

12           105. For example, on information and belief, the manufacture, use, offer for  
13 sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*,  
14 claim 1 of the ’594 patent.

15           106. Regeneron will be irreparably harmed if Amgen is not enjoined from  
16 infringing one or more claims of the ’594 patent. Regeneron is entitled to injunctive  
17 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
18 from any further infringement. Regeneron has no adequate remedy at law.

19           107. Amgen’s commercial manufacture, use, offer for sale, and/or sale within  
20 the United States, or importation into the United States, of ABP 938 before the  
21 expiration of the ’594 patent will cause Regeneron injury, entitling Regeneron to  
22 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

23           108. The submission of Amgen’s aBLA to obtain FDA approval to engage in  
24 the commercial manufacture, use, offer for sale, and/or sale within the United States,  
25 or importation into the United States, of ABP 938 before the expiration of the ’594  
26 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

**COUNT 9: INFRINGEMENT OF U.S. PATENT NO. 10,828,345 UNDER 35  
U.S.C. § 271(e)**

109. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

110. United States Patent No. 10,828,345 (“the ’345 patent”) (Exhibit 9 hereto), was duly and legally issued on November 10, 2020.

111. Regeneron is the owner of all right, title, and interest in the ’345 patent.

112. The ’345 patent has not yet expired.

113. The ’345 patent claims methods of treatment using biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(l)(3)(A).

114. The submission of Amgen’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 before the expiration of the ’345 patent is an act of infringement of one or more claims of the ’345 patent under 35 U.S.C. § 271(e)(2)(C)(i).

115. For example, the sale of ABP 938 pursuant to the label proposed in Amgen’s aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the ’345 patent.

116. Regeneron will be irreparably harmed if Amgen is not enjoined from infringing one or more claims of the ’345 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen from any further infringement. Regeneron has no adequate remedy at law.

117. Amgen’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 before the expiration of the ’345 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

118. The submission of Amgen’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States,

1 or importation into the United States, of ABP 938 before the expiration of the '345  
2 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

3 **COUNT 10: INFRINGEMENT OF U.S. PATENT NO. 10,888,601 UNDER 35**  
4 **U.S.C. § 271(e)**

5 119. Regeneron incorporates by reference all of the allegations set forth above  
6 as if fully set forth below.

7 120. United States Patent No. 10,888,601 (“the '601 patent”) (Exhibit 10  
8 hereto), was duly and legally issued on January 12, 2021.

9 121. Regeneron is the owner of all right, title, and interest in the '601 patent.

10 122. The '601 patent has not yet expired.

11 123. The '601 patent claims methods of treatment using biological products  
12 and was included on the list of patents provided by Regeneron to Amgen pursuant to  
13 42 U.S.C. § 262(l)(3)(A).

14 124. The submission of Amgen’s aBLA to obtain FDA approval to engage in  
15 the commercial manufacture, use, offer for sale, and/or sale, or import into the United  
16 States, of ABP 938 before the expiration of the '601 patent is an act of infringement  
17 of one or more claims of the '601 patent under 35 U.S.C. § 271(e)(2)(C)(i).

18 125. For example, the sale of ABP 938 pursuant to the label proposed in  
19 Amgen’s aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of  
20 the '601 patent.

21 126. Regeneron will be irreparably harmed if Amgen is not enjoined from  
22 infringing one or more claims of the '601 patent. Regeneron is entitled to injunctive  
23 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
24 from any further infringement. Regeneron has no adequate remedy at law.

25 127. Amgen’s commercial manufacture, use, offer for sale, and/or sale within  
26 the United States, or importation into the United States, of ABP 938 before the  
27 expiration of the '601 patent will cause Regeneron injury, entitling Regeneron to  
28 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

128. The submission of Amgen's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 before the expiration of the '601 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

**COUNT 11: INFRINGEMENT OF U.S. PATENT NO. 10,905,786 UNDER 35  
U.S.C. § 271(e)**

129. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

130. United States Patent No. 10,905,786 (“the ’786 patent”) (Exhibit 11 hereto), was duly and legally issued on February 2, 2021.

131. Regeneron is the owner of all right, title, and interest in the '786 patent.

132. The '786 patent has not yet expired.

133. The '786 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(l)(3)(A).

134. The submission of Amgen's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 before the expiration of the '786 patent is an act of infringement of one or more claims of the '786 patent under 35 U.S.C. § 271(e)(2)(C)(i).

135. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, inter alia, claim 15 of the '786 patent.

136. Regeneron will be irreparably harmed if Amgen is not enjoined from infringing one or more claims of the '786 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen from any further infringement. Regeneron has no adequate remedy at law.

137. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 before the



1 expiration of the '786 patent will cause Regeneron injury, entitling Regeneron to  
2 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

3 138. The submission of Amgen's aBLA to obtain FDA approval to engage in  
4 the commercial manufacture, use, offer for sale, and/or sale within the United States,  
5 or importation into the United States, of ABP 938 before the expiration of the '786  
6 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

7 **COUNT 12: INFRINGEMENT OF U.S. PATENT NO. 10,918,754 UNDER 35**  
8 **U.S.C. § 271(e)**

9 139. Regeneron incorporates by reference all of the allegations set forth above  
10 as if fully set forth below.

11 140. United States Patent No. 10,918,754 ("the '754 patent") (Exhibit 12  
12 hereto), was duly and legally issued on February 16, 2021.

13 141. Regeneron is the owner of all right, title, and interest in the '754 patent.

14 142. The '754 patent has not yet expired.

15 143. The '754 patent claims methods of making biological products and was  
16 included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C.  
17 § 262(l)(3)(A).

18 144. The submission of Amgen's aBLA to obtain FDA approval to engage in  
19 the commercial manufacture, use, offer for sale, and/or sale, or import into the United  
20 States, of ABP 938 before the expiration of the '754 patent is an act of infringement  
21 of one or more claims of the '754 patent under 35 U.S.C. § 271(e)(2)(C)(i).

22 145. For example, on information and belief, the manufacture, use, offer for  
23 sale, and/or sale, or import into the United States, of ABP 938 will infringe, inter alia,  
24 claim 1 of the '754 patent.

25 146. Regeneron will be irreparably harmed if Amgen is not enjoined from  
26 infringing one or more claims of the '754 patent. Regeneron is entitled to injunctive  
27 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
28 from any further infringement. Regeneron has no adequate remedy at law.

147. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 before the expiration of the '754 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

148. The submission of Amgen's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 before the expiration of the '754 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

**COUNT 13: INFRINGEMENT OF U.S. PATENT NO. 11,066,458 UNDER 35 U.S.C. § 271(e)**

149. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

150. United States Patent No. 11,066,458 ("the '458 patent") (Exhibit 13 hereto), was duly and legally issued on July 20, 2021.

151. Regeneron is the owner of all right, title, and interest in the '458 patent.

152. The '458 patent has not yet expired.

153. The '458 patent claims biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(l)(3)(A).

154. The submission of Amgen's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 before the expiration of the '458 patent is an act of infringement of one or more claims of the '458 patent under 35 U.S.C. § 271(e)(2)(C)(i).

155. For example, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the '458 patent.

156. Regeneron will be irreparably harmed if Amgen is not enjoined from infringing one or more claims of the '458 patent. Regeneron is entitled to injunctive

1 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
2 from any further infringement. Regeneron has no adequate remedy at law.

3 157. Amgen's commercial manufacture, use, offer for sale, and/or sale within  
4 the United States, or importation into the United States, of ABP 938 before the  
5 expiration of the '458 patent will cause Regeneron injury, entitling Regeneron to  
6 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

7 158. The submission of Amgen's aBLA to obtain FDA approval to engage in  
8 the commercial manufacture, use, offer for sale, and/or sale within the United States,  
9 or importation into the United States, of ABP 938 before the expiration of the '458  
10 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

11 **COUNT 14: INFRINGEMENT OF U.S. PATENT NO. 11,084,865 UNDER 35**  
12 **U.S.C. § 271(e)**

13 159. Regeneron incorporates by reference all of the allegations set forth above  
14 as if fully set forth below.

15 160. United States Patent No. 11,084,865 ("the '865 patent") (Exhibit 14  
16 hereto), was duly and legally issued on August 10, 2021.

17 161. Regeneron is the owner of all right, title, and interest in the '865 patent.

18 162. The '865 patent has not yet expired.

19 163. The '865 patent claims biological products and was included on the list  
20 of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(l)(3)(A).

21 164. The submission of Amgen's aBLA to obtain FDA approval to engage in  
22 the commercial manufacture, use, offer for sale, and/or sale, or import into the United  
23 States, of ABP 938 before the expiration of the '865 patent is an act of infringement  
24 of one or more claims of the '865 patent under 35 U.S.C. § 271(e)(2)(C)(i).

25 165. For example, the manufacture, use, offer for sale, and/or sale within the  
26 United States, or importation into the United States, of ABP 938 will infringe, *inter*  
27 *alia*, claim 1 of the '865 patent.



175. For example, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the '715 patent.

176. Regeneron will be irreparably harmed if Amgen is not enjoined from infringing one or more claims of the '715 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen from any further infringement. Regeneron has no adequate remedy at law.

177. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 before the expiration of the '715 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

178. The submission of Amgen's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 before the expiration of the '715 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

**COUNT 16: INFRINGEMENT OF U.S. PATENT NO. 11,160,918 UNDER 35 U.S.C. § 271(e)**

179. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

180. United States Patent No. 11,160,918 ("the '918 patent") (Exhibit 16 hereto), was duly and legally issued on November 2, 2021.

181. Regeneron is the owner of all right, title, and interest in the '918 patent.

182. The '918 patent has not yet expired.

183. The '918 patent claims biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(l)(3)(A).

184. The submission of Amgen's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 before the expiration of the '918 patent is an act of infringement of one or more claims of the '918 patent under 35 U.S.C. § 271(e)(2)(C)(i).

1 185. For example, on information and belief, the manufacture, use, offer for  
2 sale, and/or sale within the United States, or importation into the United States, of  
3 ABP 938 will infringe, *inter alia*, claim 1 of the '918 patent.

4 186. Regeneron will be irreparably harmed if Amgen is not enjoined from  
5 infringing one or more claims of the '918 patent. Regeneron is entitled to injunctive  
6 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
7 from any further infringement. Regeneron has no adequate remedy at law.

8 187. Amgen's commercial manufacture, use, offer for sale, and/or sale within  
9 the United States, or importation into the United States, of ABP 938 before the  
10 expiration of the '918 patent will cause Regeneron injury, entitling Regeneron to  
11 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

12 188. The submission of Amgen's aBLA to obtain FDA approval to engage in  
13 the commercial manufacture, use, offer for sale, and/or sale within the United States,  
14 or importation into the United States, of ABP 938 before the expiration of the '918  
15 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

16 **COUNT 17: INFRINGEMENT OF U.S. PATENT NO. 11,253,572 UNDER 35**  
17 **U.S.C. § 271(e)**

18 189. Regeneron incorporates by reference all of the allegations set forth above  
19 as if fully set forth below.

20 190. United States Patent No. 11,253,572 ("the '572 patent") (Exhibit 17  
21 hereto), was duly and legally issued on February 22, 2022.

22 191. Regeneron is the owner of all right, title, and interest in the '572 patent.

23 192. The '572 patent has not yet expired.

24 193. The '572 patent claims methods of treatment using biological products  
25 and was included on the list of patents provided by Regeneron to Amgen pursuant to  
26 42 U.S.C. § 262(l)(3)(A).

27 194. The submission of Amgen's aBLA to obtain FDA approval to engage in  
28 the commercial manufacture, use, offer for sale, and/or sale, or import into the United

1 States, of ABP 938 before the expiration of the '572 patent is an act of infringement  
2 of one or more claims of the '572 patent under 35 U.S.C. § 271(e)(2)(C)(i).

3 195. For example, the sale of ABP 938 pursuant to the label proposed in  
4 Amgen's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of  
5 the '572 patent.

6 196. Regeneron will be irreparably harmed if Amgen is not enjoined from  
7 infringing one or more claims of the '572 patent. Regeneron is entitled to injunctive  
8 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
9 from any further infringement. Regeneron has no adequate remedy at law.

10 197. Amgen's commercial manufacture, use, offer for sale, and/or sale within  
11 the United States, or importation into the United States, of ABP 938 before the  
12 expiration of the '572 patent will cause Regeneron injury, entitling Regeneron to  
13 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

14 198. The submission of Amgen's aBLA to obtain FDA approval to engage in  
15 the commercial manufacture, use, offer for sale, and/or sale within the United States,  
16 or importation into the United States, of ABP 938 before the expiration of the '572  
17 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

18 **COUNT 18: INFRINGEMENT OF U.S. PATENT NO. 11,306,135 UNDER 35**  
19 **U.S.C. § 271(e)**

20 199. Regeneron incorporates by reference all of the allegations set forth above  
21 as if fully set forth below.

22 200. United States Patent No. 11,306,135 ("the '135 patent") (Exhibit 18  
23 hereto), was duly and legally issued on April 19, 2022.

24 201. Regeneron is the owner of all right, title, and interest in the '135 patent.

25 202. The '135 patent has not yet expired.

26 203. The '135 patent claims biological products and was included on the list  
27 of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(l)(3)(A).  
28







1 221. Regeneron is the owner of all right, title, and interest in the '861 patent.

2 222. The '861 patent has not yet expired.

3 223. The '861 patent claims methods of making biological products and was  
4 included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C.  
5 § 262(l)(3)(A).

6 224. The submission of Amgen's aBLA to obtain FDA approval to engage in  
7 the commercial manufacture, use, offer for sale, and/or sale, or import into the United  
8 States, of ABP 938 before the expiration of the '861 patent is an act of infringement  
9 of one or more claims of the '861 patent under 35 U.S.C. § 271(e)(2)(C)(i).

10 225. For example, the manufacture, use, offer for sale, and/or sale, or import  
11 into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the '861 patent.

12 226. Regeneron will be irreparably harmed if Amgen is not enjoined from  
13 infringing one or more claims of the '861 patent. Regeneron is entitled to injunctive  
14 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
15 from any further infringement. Regeneron has no adequate remedy at law.

16 227. Amgen's commercial manufacture, use, offer for sale, and/or sale within  
17 the United States, or importation into the United States, of ABP 938 before the  
18 expiration of the '861 patent will cause Regeneron injury, entitling Regeneron to  
19 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

20 228. The submission of Amgen's aBLA to obtain FDA approval to engage in  
21 the commercial manufacture, use, offer for sale, and/or sale within the United States,  
22 or importation into the United States, of ABP 938 before the expiration of the '861  
23 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

24 **COUNT 21: INFRINGEMENT OF U.S. PATENT NO. 11,505,593 UNDER 35**  
25 **U.S.C. § 271(e)**

26 229. Regeneron incorporates by reference all of the allegations set forth above  
27 as if fully set forth below.

1           230. United States Patent No. 11,505,593 (“the ’593 patent”) (Exhibit 21  
2 hereto), was duly and legally issued on November 22, 2022.

3           231. Regeneron is the owner of all right, title, and interest in the ’593 patent.

4           232. The ’593 patent has not yet expired.

5           233. The ’593 patent claims biological products and was included on the list  
6 of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(l)(3)(A).

7           234. The submission of Amgen’s aBLA to obtain FDA approval to engage in  
8 the commercial manufacture, use, offer for sale, and/or sale, or import into the United  
9 States, of ABP 938 before the expiration of the ’593 patent is an act of infringement  
10 of one or more claims of the ’593 patent under 35 U.S.C. § 271(e)(2)(C)(i).

11           235. For example, the manufacture, use, offer for sale, and/or sale, or import  
12 into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the ’593 patent.

13           236. Regeneron will be irreparably harmed if Amgen is not enjoined from  
14 infringing one or more claims of the ’593 patent. Regeneron is entitled to injunctive  
15 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
16 from any further infringement. Regeneron has no adequate remedy at law.

17           237. Amgen’s commercial manufacture, use, offer for sale, and/or sale within  
18 the United States, or importation into the United States, of ABP 938 before the  
19 expiration of the ’593 patent will cause Regeneron injury, entitling Regeneron to  
20 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

21           238. The submission of Amgen’s aBLA to obtain FDA approval to engage in  
22 the commercial manufacture, use, offer for sale, and/or sale within the United States,  
23 or importation into the United States, of ABP 938 before the expiration of the ’593  
24 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

**COUNT 22: INFRINGEMENT OF U.S. PATENT NO. 11,535,663 UNDER 35  
U.S.C. § 271(e)**

239. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

240. United States Patent No. 11,535,663 (“the ’663 patent”) (Exhibit 22 hereto), was duly and legally issued on December 27, 2022.

241. Regeneron is the owner of all right, title, and interest in the ’663 patent.

242. The ’663 patent has not yet expired.

243. The ’663 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(l)(3)(A).

244. The submission of Amgen’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 before the expiration of the ’663 patent is an act of infringement of one or more claims of the ’663 patent under 35 U.S.C. § 271(e)(2)(C)(i).

245. For example, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the ’663 patent.

246. Regeneron will be irreparably harmed if Amgen is not enjoined from infringing one or more claims of the ’663 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen from any further infringement. Regeneron has no adequate remedy at law.

247. Amgen’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 before the expiration of the ’663 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

248. The submission of Amgen’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States,

1 or importation into the United States, of ABP 938 before the expiration of the '663  
2 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

3 **COUNT 23: INFRINGEMENT OF U.S. PATENT NO. 11,542,317 UNDER 35**  
4 **U.S.C. § 271(e)**

5 249. Regeneron incorporates by reference all of the allegations set forth above  
6 as if fully set forth below.

7 250. United States Patent No. 11,542,317 (“the ’317 patent”) (Exhibit 23  
8 hereto), was duly and legally issued on January 3, 2023.

9 251. Regeneron is the owner of all right, title, and interest in the ’317 patent.

10 252. The ’317 patent has not yet expired.

11 253. The ’317 patent claims biological products and methods of treatment  
12 using biological products and was included on the list of patents provided by  
13 Regeneron to Amgen pursuant to 42 U.S.C. § 262(l)(3)(A).

14 254. The submission of Amgen’s aBLA to obtain FDA approval to engage in  
15 the commercial manufacture, use, offer for sale, and/or sale, or import into the United  
16 States, of ABP 938 before the expiration of the ’317 patent is an act of infringement  
17 of one or more claims of the ’317 patent under 35 U.S.C. § 271(e)(2)(C)(i).

18 255. For example, the manufacture, use, offer for sale, and/or sale, or import  
19 into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the ’317 patent.

20 256. Regeneron will be irreparably harmed if Amgen is not enjoined from  
21 infringing one or more claims of the ’317 patent. Regeneron is entitled to injunctive  
22 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
23 from any further infringement. Regeneron has no adequate remedy at law.

24 257. Amgen’s commercial manufacture, use, offer for sale, and/or sale within  
25 the United States, or importation into the United States, of ABP 938 before the  
26 expiration of the ’317 patent will cause Regeneron injury, entitling Regeneron to  
27 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).





1 expiration of the '932 patent will cause Regeneron injury, entitling Regeneron to  
2 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

3 268. The submission of Amgen's aBLA to obtain FDA approval to engage in  
4 the commercial manufacture, use, offer for sale, and/or sale within the United States,  
5 or importation into the United States, of ABP 938 before the expiration of the '932  
6 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

7 **COUNT 25: INFRINGEMENT OF U.S. PATENT NO. 11,555,176 UNDER 35**  
8 **U.S.C. § 271(e)**

9 269. Regeneron incorporates by reference all of the allegations set forth above  
10 as if fully set forth below.

11 270. United States Patent No. 11,555,176 ("the '176 patent") (Exhibit 25  
12 hereto), was duly and legally issued on January 17, 2023.

13 271. Regeneron is the owner of all right, title, and interest in the '176 patent.

14 272. The '176 patent has not yet expired.

15 273. The '176 patent claims methods of making biological products and was  
16 included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C.  
17 § 262(l)(3)(A).

18 274. The submission of Amgen's aBLA to obtain FDA approval to engage in  
19 the commercial manufacture, use, offer for sale, and/or sale, or import into the United  
20 States, of ABP 938 before the expiration of the '176 patent is an act of infringement  
21 of one or more claims of the '176 patent under 35 U.S.C. § 271(e)(2)(C)(i).

22 275. For example, on information and belief, the manufacture, use, offer for  
23 sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*,  
24 claim 20 of the '176 patent.

25 276. Regeneron will be irreparably harmed if Amgen is not enjoined from  
26 infringing one or more claims of the '176 patent. Regeneron is entitled to injunctive  
27 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
28 from any further infringement. Regeneron has no adequate remedy at law.

277. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 before the expiration of the '176 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

278. The submission of Amgen's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 before the expiration of the '176 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

**COUNT 26: INFRINGEMENT OF U.S. PATENT NO. 11,559,564 UNDER 35  
U.S.C. § 271(e)**

279. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

280. United States Patent No. 11,559,564 (“the ’564 patent”) (Exhibit 26 hereto), was duly and legally issued on January 24, 2023.

281. Regeneron is the owner of all right, title, and interest in the '564 patent.

282. The '564 patent has not yet expired.

283. The '564 patent claims methods of treatment using biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(l)(3)(A).

284. The submission of Amgen's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 before the expiration of the '564 patent is an act of infringement of one or more claims of the '564 patent under 35 U.S.C. § 271(e)(2)(C)(i).

285. For example, the sale of ABP 938 pursuant to the label proposed in Amgen's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '564 patent.

286. Regeneron will be irreparably harmed if Amgen is not enjoined from infringing one or more claims of the '564 patent. Regeneron is entitled to injunctive

1 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
2 from any further infringement. Regeneron has no adequate remedy at law.

3 287. Amgen's commercial manufacture, use, offer for sale, and/or sale within  
4 the United States, or importation into the United States, of ABP 938 before the  
5 expiration of the '564 patent will cause Regeneron injury, entitling Regeneron to  
6 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

7 288. The submission of Amgen's aBLA to obtain FDA approval to engage in  
8 the commercial manufacture, use, offer for sale, and/or sale within the United States,  
9 or importation into the United States, of ABP 938 before the expiration of the '564  
10 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

11 **COUNT 27: INFRINGEMENT OF U.S. PATENT NO. 11,680,930 UNDER 35**  
12 **U.S.C. § 271(e)**

13 289. Regeneron incorporates by reference all of the allegations set forth above  
14 as if fully set forth below.

15 290. United States Patent No. 11,680,930 ("the '930 patent") (Exhibit 27  
16 hereto), was duly and legally issued on June 20, 2023.

17 291. Regeneron is the owner of all right, title, and interest in the '930 patent.

18 292. The '930 patent has not yet expired.

19 293. The '930 patent claims methods used in making biological products and  
20 was included on the list of patents provided by Regeneron to Amgen pursuant to 42  
21 U.S.C. § 262(l)(3)(A).

22 294. The submission of Amgen's aBLA to obtain FDA approval to engage in  
23 the commercial manufacture, use, offer for sale, and/or sale, or import into the United  
24 States, of ABP 938 before the expiration of the '930 patent is an act of infringement  
25 of one or more claims of the '930 patent under 35 U.S.C. § 271(e)(2)(C)(i).

26 295. For example, on information and belief, the manufacture, use, offer for  
27 sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*,  
28 claim 1 of the '930 patent.





1 States, of ABP 938 before the expiration of the '459 patent is an act of infringement  
2 of one or more claims of the '459 patent under 35 U.S.C. § 271(e)(2)(C)(i).

3 315. For example, on information and belief, the manufacture, use, offer for  
4 sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*,  
5 claim 1 of the '459 patent.

6 316. Regeneron will be irreparably harmed if Amgen is not enjoined from  
7 infringing one or more claims of the '459 patent. Regeneron is entitled to injunctive  
8 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
9 from any further infringement. Regeneron has no adequate remedy at law.

10 317. Amgen's commercial manufacture, use, offer for sale, and/or sale within  
11 the United States, or importation into the United States, of ABP 938 before the  
12 expiration of the '459 patent will cause Regeneron injury, entitling Regeneron to  
13 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

14 318. The submission of Amgen's aBLA to obtain FDA approval to engage in  
15 the commercial manufacture, use, offer for sale, and/or sale within the United States,  
16 or importation into the United States, of ABP 938 before the expiration of the '459  
17 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

18 **COUNT 30: INFRINGEMENT OF U.S. PATENT NO. 11,769,597 UNDER 35**  
19 **U.S.C. § 271(e)**

20 319. Regeneron incorporates by reference all of the allegations set forth above  
21 as if fully set forth below.

22 320. United States Patent No. 11,769,597 ("the '597 patent") (Exhibit 30  
23 hereto), was duly and legally issued on September 26, 2023.

24 321. Regeneron is the owner of all right, title, and interest in the '597 patent.

25 322. The '597 patent has not yet expired.

26 323. The '597 patent claims methods of treatment using biological products  
27 and was included on the list of patents provided by Regeneron to Amgen pursuant to  
28 42 U.S.C. § 262(l)(3)(A).





1           333. The '102 patent claims methods of making biological products and was  
2 included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C.  
3 § 262(l)(3)(A).

4           334. The submission of Amgen's aBLA to obtain FDA approval to engage in  
5 the commercial manufacture, use, offer for sale, and/or sale, or import into the United  
6 States, of ABP 938 before the expiration of the '102 patent is an act of infringement  
7 of one or more claims of the '102 patent under 35 U.S.C. § 271(e)(2)(C)(i).

8           335. For example, on information and belief, the manufacture, use, offer for  
9 sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*,  
10 claim 21 of the '102 patent.

11           336. Regeneron will be irreparably harmed if Amgen is not enjoined from  
12 infringing one or more claims of the '102 patent. Regeneron is entitled to injunctive  
13 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
14 from any further infringement. Regeneron has no adequate remedy at law.

15           337. Amgen's commercial manufacture, use, offer for sale, and/or sale within  
16 the United States, or importation into the United States, of ABP 938 before the  
17 expiration of the '102 patent will cause Regeneron injury, entitling Regeneron to  
18 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

19           338. The submission of Amgen's aBLA to obtain FDA approval to engage in  
20 the commercial manufacture, use, offer for sale, and/or sale within the United States,  
21 or importation into the United States, of ABP 938 before the expiration of the '102  
22 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

23           **COUNT 32: INFRINGEMENT OF U.S. PATENT NO. 11,793,926**

24                           **UNDER 35 U.S.C. § 271(e)**

25           339. Regeneron incorporates by reference all of the allegations set forth above  
26 as if fully set forth below.

27           340. United States Patent No. 11,793,926 ("the '926 patent") (Exhibit 32  
28 hereto), was duly and legally issued on October 24, 2023.

1           341. Regeneron is the owner of all right, title, and interest in the '926 patent.

2           342. The '926 patent has not yet expired.

3           343. The '926 patent claims packaging for biological products and was  
4 included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C.  
5 § 262(l)(3)(A).

6           344. The submission of Amgen's aBLA to obtain FDA approval to engage in  
7 the commercial manufacture, use, offer for sale, and/or sale, or import into the United  
8 States, of ABP 938 before the expiration of the '926 patent is an act of infringement  
9 of one or more claims of the '926 patent under 35 U.S.C. § 271(e)(2)(C)(i).

10           345. For example, on information and belief, the manufacture, use, offer for  
11 sale, and/or sale within the United States, or importation into the United States, of  
12 ABP 938 will infringe, *inter alia*, claim 11 of the '926 patent.

13           346. Regeneron will be irreparably harmed if Amgen is not enjoined from  
14 infringing one or more claims of the '926 patent. Regeneron is entitled to injunctive  
15 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen  
16 from any further infringement. Regeneron has no adequate remedy at law.

17           347. Amgen's commercial manufacture, use, offer for sale, and/or sale within  
18 the United States, or importation into the United States, of ABP 938 before the  
19 expiration of the '926 patent will cause Regeneron injury, entitling Regeneron to  
20 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

21           348. The submission of Amgen's aBLA to obtain FDA approval to engage in  
22 the commercial manufacture, use, offer for sale, and/or sale within the United States,  
23 or importation into the United States, of ABP 938 before the expiration of the '926  
24 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

25                                   **PRAYER FOR RELIEF**

26                   WHEREFORE, Regeneron requests the following relief:

27                   (a)   A judgment that Amgen has infringed the patents in suit;

1 (b) Permanent equitable relief, pursuant to 35 U.S.C. § 271(e)(4)(B),  
2 including but not limited to a permanent injunction that enjoins Amgen, its officers,  
3 partners, agents, servants, employees, parents, subsidiaries, affiliate corporations,  
4 other related business entities, and all other persons acting in concert, participation,  
5 or in privity with them and/or their successors or assigns from infringing the patents  
6 in suit, or contributing to the same, or actively inducing anyone to do the same, by  
7 acts including the manufacture, use, offer to sell, sale, distribution, or importation of  
8 any current or future versions of a product that infringes, or the use or manufacturing  
9 of which infringes, the patents in suit;

10 (c) Preliminary equitable relief, pursuant to 35 U.S.C. § 271(e)(4)(B),  
11 including but not limited to a preliminary injunction that enjoins Amgen, its officers,  
12 partners, agents, servants, employees, parents, subsidiaries, affiliate corporations,  
13 other related business entities, and all other persons acting in concert, participation,  
14 or in privity with them and/or their successors or assigns from infringing the patents  
15 in suit, or contributing to the same, or actively inducing anyone to do the same, by  
16 acts including the manufacture, use, offer to sell, sale, distribution, or importation of  
17 any current or future versions of a product that infringes, or the use or manufacturing  
18 of which infringes, the patents in suit;

19 (d) Statutory relief under 35 U.S.C. § 271(e)(4)(D), including but not  
20 limited to a permanent injunction prohibiting Amgen, its officers, partners, agents,  
21 servants, employees, parents, subsidiaries, affiliate corporations, other related  
22 business entities, and all other persons acting in concert, participation, or in privity  
23 with them and/or their successors or assigns from infringing the patents in suit, or  
24 contributing to the same, or actively inducing anyone to do the same, by acts including  
25 the manufacture, use, offer to sell, sale, distribution, or importation of any current or  
26 future versions of a product that infringes, or the use or manufacturing of which  
27 infringes, the patents in suit;  
28

1 (e) Damages pursuant to 35 U.S.C. § 271(e)(4)(C), if applicable, in  
2 the form of lost profits but in no event less than a reasonable royalty;

3 (f) A judgment that the infringement has been willful and an  
4 enhancement of damages;

5 (g) An award for an accounting of damages from Amgen's infringement;

6 (h) A declaration that this is an exceptional case and an award of  
7 attorneys' fees pursuant to 35 U.S.C. § 285 and 35 U.S.C. 271§ (e)(4);

8 (i) An award of Regeneron's costs and expenses in this action; and

9 (j) Such further relief as this court may deem just and proper.  
10

11  
12 Respectfully submitted,

13  
14 Dated: January 10, 2024

**BIENERT KATZMAN**  
**LITRELL WILLIAMS LLP**

15  
16 /s/ Anthony R. Bisconti

17 Anthony R. Bisconti

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